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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mark J. Redmond

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

11/18/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/567,823	Applicant(s) REDMOND ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2pgs (2/10/06), 3pgs (11/02/06), 2pgs (04/22/10).

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I, claims 1-14, in the reply filed on 8/30/2010 is acknowledged.

Claims 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Objections

Claims 4-14 are objected to because of the following informalities:

Claim 4 recites in section (a) about 35 to about 55 percent by weight "glycemic polysaccharide" and then in section (b) about 10 to about 35 percent by weight mono- and disaccharides, "said mono- and di-saccharides comprising the glycemic carbohydrate".

The final recitation is confusing as Applicants define "glycemic polysaccharide" in the instant specification to be a subgenus within "glycemic carbohydrates" (see instant specification pg 16 line 33 spanning pg 17 line 2). As such, it is unclear how the mono- and di-saccharides are comprised of glycemic carbohydrates, where glycemic carbohydrates is broader than mono- and di-saccharides. Further, it is unclear how the mono- and di-saccharides can be present at the recited weight percent when the glycemic polysaccharides be within the genus of "glycemic carbohydrates" and be at a higher weight percent than permitted in section (a).

As Applicants appear to be claiming the complex (poly-) saccharides in section (a) and simple (mono- and di-) saccharides in section (b) separately, Examiner suggests removing the phrase “said mono- and di-saccharides comprising the glycemic carbohydrates” from lines 4-5 of claim 4.

For purposes of examination, the two components will be construed as distinct components because some the dependant claims further define the ratio of components (a) and (b).

Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefinite

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 14 use the term “derived” to define the glycemic polysaccharide. The term “derived” renders the claims indefinite because it is unclear what relation is required between the glycemic polysaccharide and the grain crops listed. For example, the natural glycemic polysaccharide could be further modified and still read on “derived” or it could require the saccharides be made only from the natural grain products listed, i.e. natural versus synthetic.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Astbury et al (X-Ray Comparison of Natural and Synthetic Starch, Nature, Vol 146, (1940) pg 558).

Astbury et al teaches synthetic starches were prepared in vitro (pg 558, first paragraph). As the product is prepared in vitro using glucose-1-phosphat and the enzyme phosphorylase, no fiber would be present like starches isolated from naturally occurring grains by grinding and separation.

Note, the recitation “an oral diagnostic test meal” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, the claims read on starch, per se, which does not require the preamble for completeness.

Additionally, the recited functional property of the composition, i.e. to provide a “quantity of glycemic carbohydrate effective to increase blood glucose levels”, would

Art Unit: 1612

reasonably be expected to be inherent, given Applicants admit the physiological effect of ingesting starches is the break down into glucose, which in turn is absorbed into the body, raising blood glucose levels (see instant specification pg 16 line 33 spanning pg 17 line 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-7 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmason et al (WO 97/02050, see IDS dated 2/10/06) in view of Wursch et al (The Role of Viscous Soluble Fiber in the Metabolic Control of Diabetes, Diabetes Care, V. 20, No. 1 (1997) pp1774-1780, see IDS dated 11/02/06).

Palmason et al teaches meals for diabetic testing comprising (1) carbohydrates, preferably complex carbohydrates; (2) fat content, preferably low in saturated fat, e.g. less than about 10-30% of the total fat energy, and high in monounsaturated fat, e.g. 25-75% of the total fat energy; and optional fiber content (pg 16 lines 21-34). Within

Art Unit: 1612

these guidelines, Palmason et al teaches an example formulation of a test bar comprising 98 gram solid oral carbohydrate test meal comprising 11.6g fat, 12.2 grams protein, 40.5g oat starch, 9.5 grams sugars, 5.9 grams of fiber, and flavoring (pg 29 Example 3).

Palmason et al does not disclose a specific embodiment with less than 0.5% soluble fiber, the specific ratios instantly recited in claims 5-7, or the specific ratio of saturated to monounsaturated fats.

Wursch et al is teaches that the addition of soluble fiber, especially beta.glucan, was known to increase the viscosity of the meal bolus once it reaches the small intestine, thereby delaying meal absorption and producing a 50% reduction in the glycemic peak (abstract).

Wursch et al does not teach the specific combination of components instantly recited..

Where the addition of fiber is optional, as taught by Palmason et al, it would have been obvious to one of ordinary skill in the art to either include or not include the fiber when formulating the test meal compositions of the Palmason et al. Further, the skilled artisan would have been motivated not include soluble fiber in the test meals of Palmason et al based on the teaching of Wursch et al, given the delay in absorption of glucose would result in an almost 50% reduction in glycemic peak, rendering the test meal of Palmason et al less effective for determining the glycol response than with the soluble fiber present.

Further, wither regards to claims 5-7, the prior art does not disclose the exact claimed ratios of complex to simple saccharides, but does teach a working embodiment which contains a combination of the two. That disclosure, coupled with teaching that complex saccharides are favored over simple saccharides, would provide motivation to the skilled artisan to optimize the two forms of glucose producing components, given their intended use in the composition is to provide a biological indicator of the glucose response (pg 33 Example 6).

Finally, with regards to claim 10, where Palmason et al does not disclose the exact claimed ranges for saturated to monounsaturated fats, but the taught ranges do overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmason et al (WO 97/02050, see IDS dated 2/10/06) in view of Wursch et al (The Role of Viscous Solbule Fiber in the Metabolic Control of Diabetes, Diabetes Care, V. 20, No. 1 (1997) pp1774-1780, see IDS dated 11/02/06), the combination in view of Fuisz (US 5,422,136).

Palmason et al and Wurst et al are discussed above, but do not disclose specific common simple saccharides.

Fuisz (US 5,472,731) teaches common saccharides suitable for oral administration with starch include sucrose and fructose (col 5 lines 10-14 and 28-29).

Art Unit: 1612

Fuisz does not teach the other instantly claimed components as part of the composition.

It would have been obvious to one of ordinary skill in the art when selecting simple saccharides for the composition in Palmason et al to use known simple saccharides which are suitable for administration in combination with starches, such as disclosed in Fuisz, given their suitability for oral ingestion and their disclosed compatibility with the major component of the primary composition, i.e. starches

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612